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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,552	02/12/2004	Daniel A. Hammer	UPN-4290	6019

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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
09/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,552	HAMMER ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-184* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10-13,15-23,32-42,46,52-55,60-63,65,70-75,79 and 88-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 6-9,14,24-31,43-45,47-51,56-59,64,66-69,76,77,80-87 and 102-184.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 6/11/2007, in reply to the Office Action mailed 2/12/2007, is acknowledged and has been entered. Claims 1 – 184 are pending, of which claims 6 – 9, 14, 24 – 31, 43 – 45, 47 – 51, 56 – 59, 64, 66 – 69, 76, 77, 80 – 87 and 102 – 184 are withdrawn from consideration at this time as being drawn to a non-elected invention. Claims 1, 8, 16, 17, 19, 21, 52, 55, 58, 70, 71, 73, 75, 107, 115, 119, 131, 139, 153, 166 and 170 have been amended. Claims 1 – 5, 10 – 13, 15 – 23, 32 – 42, 46, 52 – 55, 60 – 63, 65, 70 – 75, 79 and 88 – 101 are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

The rejection of claims 1, 2, 15, 22, 23, 32 – 42, and 46 under 35 U.S.C. § 102 as being anticipated by Lee *et al.* (*Biotechnol. and Bioeng.*, 2001, 73, p. 135 – 145) is withdrawn as having been overcome by amendment.

Applicant's arguments filed 6/11/2007, with respect to the rejection of claims 1 – 4, 15, 22, 23, 32 – 42, 46, 52 – 55, 65, 74, 78, 79 and 88 – 101 under 35 U.S.C. § 103 as being unpatentable over Unger (US 6,123,923) in view of Lee *et al.*; the rejection of claims 1 – 4, 15, 22, 23, 32 – 42 and 46 under 35 U.S.C. § 103 as being unpatentable over Klaveness (US 6,159,445) in view of Lee *et al.*; and the rejection of claims 1 – 5, 10 – 13, 15 – 23, 32 – 42, 46, 52 – 55, 60 – 63, 65, 70 – 75, 78, 79 and 88 – 101 under

35 U.S.C. § 103 as being unpatentable over Unger and Klaveness, in view of Lee, in further view of Lin *et al.* (*Chem. Eur. J.*, 1995, 1, p. 645 – 651), have been fully considered but they are not persuasive for reasons set forth hereinbelow.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 – 4, 15, 22, 23, 32 – 42, 46, 52 – 55, 65, 74, 78, 79 and 88 – 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 6,123,923) in view of Lee *et al.* (*Biotechnol. and Bioeng.*, 2001, 73, p. 135 – 145), for reasons set forth in the office action mailed 2/12/2007.

Applicant argues on page 32 of the Response that the Unger patent does not teach an emissive agent which emits light in the 600 – 1100 nm spectral regime.

This is non-persuasive because Unger teaches vesicles comprising a photoactive agent such as those active in the infrared wavelength, from about 500 to about 1400 nm (claims 8 and 9). See also column 11, lines 26 – 46, wherein the photoactive agent is active from 730 nm to 1300 nm, or specific emissive agents in column 12 – 13.

Claims 1 – 4, 15, 22, 23, 32 – 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness (US 6,159,445) in view of Lee *et al.* (*Biotechnol.*

and Bioeng., 2001, 73, p. 135 – 145), for reasons set forth in the office action mailed 2/12/2007.

Applicant argues on page 32 of the Response that the Klaveness patent nor the Lee article teach an emissive agent which emits light in the 600 – 1100 nm spectral regime.

This is non-persuasive because Klaveness teaches that the most interesting wavelengths for light imaging techniques are in the approximate range of 600 – 1300 nm, and specifically teaches that vesicles comprising a chromophore or fluorophore having absorption/emission maxima particularly preferred for *in vivo* light imaging, including porphyrins, etc. See column 3, lines 25 – 33; column 10, lines 9 – 29; column 16, lines 1 – 20.

Claims 1 – 5, 10 – 13, 15 – 23, 32 – 42, 46, 52 – 55, 60 – 63, 65, 70 – 75, 78, 79 and 88 – 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (6,123,923) and Klaveness (6,159,445), in view of Lee *et al.* (*Biotechnol. and Bioeng.*, 2001, 73, p. 135 – 145), in further view of Lin *et al.* (*Chem. Eur. J.*, 1995, 1, p. 645 – 651), for reasons set forth in the office action mailed 2/12/2007.

Applicant argues on pages 32 – 33 of the Response that the Klaveness and Unger patents fail to teach or suggest the emissive agent of the amended claims.

This is non-persuasive because both Unger and Klaveness teach vesicles for light imaging comprising emissive agents, including porphyrins, etc., having absorption/emission maxima within the claimed range, as discussed above.

Applicant argues that there is no motivation to make the combination of changes needed to the Klaveness and Unger patents (i.e. substitution of amphiphilic copolymers, as in the Lee article, and substitution of a porphyrin moiety as the emissive agent.

This is not found persuasive because the combined teachings of the cited art provide motivation for the instant claims. For example, one would have been motivated to utilize polymersomes comprising amphiphilic diblock copolymers as the vesicles which contain a chromophore or fluorophore in the light imaging agents of Unger or Klaveness comprising liposome or polymeric vesicles because Lee teaches that such polymersomes are superior to traditional or "stealth" liposomes for encapsulation technologies because of their thicker, more robust membranes. Such polymersomes are biocompatible, non-toxic in cell culture, and are capable of incorporating an emissive agent within the membrane for fluorescence imaging. Regarding the emissive agent of claims 5, 10 – 13, 16 – 21, etc., it would have been obvious to use an emissive agent comprising two porphyrin moieties linked by an unsaturated hydrocarbon as the fluorophore or chromophore contained within the vesicles of Klaveness or Unger because Klaveness teaches the importance of utilizing an emissive agent, including porphyrin, etc., having an absorption/emission maximum in the range of 600 – 1300 nm because these wavelengths have the ability to penetrate relatively deeply into living tissue without absorption by natural substances and are harmless to the human body (column 3, lines 25 – 33), as well as the importance of high quantum yield for fluorescence (column 16), and because Lin teaches ethynyl-bridged porphyrins as

having absorption around 800 nm, which may be used as optical probes, sensitizers, etc.

Applicant argues that the contrast agents recited in the Lee article and the Unger and Klaveness patents would be inferior at the end uses claimed in the instant application, because at the lower wavelengths of the agents of the cited art, the agents are useful for imaging vesicle structure, but due to scattering considerations would not be good at *in vivo* detection of the delivery of pharmaceutical agents to a site within a patient.

This is non-persuasive because Klaveness and Unger both specifically teach vesicles for light imaging comprising emissive agents, including porphyrins, etc., having absorption/emission maxima, such as 600 – 1300 nm, as discussed above.

Conclusion

No claims are allowed at this time.

Although Applicant's arguments as set forth in the aforementioned Response have been fully considered, they are deemed unpersuasive. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER